

## REMARKS

### **I. Introduction**

In response to the Office Action dated October 7, 2005, claims 1 and 2 have been amended, and new claim 9 has been added. Claims 1-9 remain in the application. Reconsideration of the application, as amended, is requested.

### **II. Claim Amendments**

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter or raise new issues. The amendments are supported by the application as originally filed, as indicated below. Entry of these amendments is respectfully requested.

The amendment to claim 1 is supported by the specification at page 2, lines 11-13.

The amendment to claim 2 is supported by the specification at page 8, lines 1-4.

New claim 9 is supported by the specification at page 8, lines 13-15.

### **III. Non-Art Rejections**

On page (5) of the Office Action, claim 2 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The amendment of claim 2 renders this rejection moot.

### **IV. Prior Art Rejections**

On page (3) of the Office Action, claims 1-5 and 7 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ory et al., PNAS, 1996, Vol. 93, pages 11400-11406 (Ory). On page (5) of the Office Action, claims 1-3 and 5-6 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Gruber et al., U.S. Patent No. 5,503,974 (Gruber). On page (6) of the Office Action, claims 1-7 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Gruber and Ory.

The amendment to claim 1 renders these rejections moot.

#### A. The claimed invention

Independent claim 1 is generally directed to a method that requires integrating a transgene encoding a virus envelope into the genome of a cell to produce an indicator cell and contacting the indicator cell so produced with a vector batch to be screened for presence of exogenous envelope-defective retrovirus. This method provides a sensitive screening system to identify envelope-defective recombinant viruses that can originate during production of lentiviral or retroviral vectors. The invention addresses a need for detecting such contaminants that might otherwise go undetected. This method allows one to validate and maintain the performance of a vector producer system, as well as to prove the purity and safety of a vector batch.

#### B. Novelty

The cited references do not teach nor suggest these various elements of Applicants' independent claims. Ory describes packaging cell lines for production of vesicular stomatitis virus G (VSV G) pseudotyped recombinant Moloney murine leukemia virus particles. The teaching of Ory does not relate to or otherwise suggest screening a vector batch for contaminants. Without teaching each element of Applicants' claims, Ory cannot anticipate the claimed invention.

#### C. Nonobviousness

Gruber is directed at detecting intact retroviruses in a specimen by use of replication defective retroviral construct having a marker sequence. Ory, as mentioned above, describes packaging cell lines for production of vesicular stomatitis virus G (VSV G) pseudotyped recombinant Moloney murine leukemia virus particles. These references are directed at methods that do not involve or suggest use of an indicator cell into which a transgene encoding a virus envelope has been integrated into the genome to detect envelope-defective retrovirus and using such an indicator cell to screen a vector batch for purity and safety.

Moreover, the prior art does not contemplate the development of a screening method having the sensitivity explicitly recited in new claim 9, nor does it teach or suggest the measurement

of defective retrovirus in a vector batch. Use of such a method defined by these dependent claims is even further removed from the cited references.

Accordingly, Applicants respectfully request withdrawal of the rejections based on the prior art.

V. Conclusion

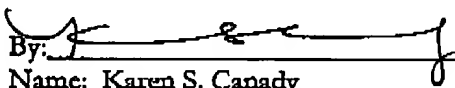
In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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Date: January 5, 2006

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